

K120977

SECTION 5: 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SDMA 1990 and 21 CFR 807.92.

JUL 03 2013

[A] 807.92 (a)(1): Submitter

Name: International Technidyne Corporation
Address: 23 Nevsky Street Edison, NJ 08820
Phone: (732) 548-5700, FAX: (732) 635-0144
Contact: Larry Picciano, Director of Regulatory Affairs

[B] 807.92 (a)(2): Device name - Trade Name and Common Name, and Classification

Trade name: directCHECK® Whole Blood Control for HEMOCHRON® ACT+ assay
Trade name: directCHECK® Whole Blood Control for HEMOCHRON® ACT-LR assay
Common Name: Whole blood controls for in vitro diagnostic coagulation systems
Classification: Class II, 21 CFR § 864.5425
Product Code: GGN, Plasma, Coagulation Control

[C] 807.92 (a) (3): Identification of the Legally Marketed Predicate Devices

Trade name: HEMOCHRON® Jr. Microcoagulation Low Range ACT including whole blood controls Normal / Abnormal
510(k) number: K960749
Manufacturer: International Technidyne Corporation (ITC), Edison, NJ
Trade name: HEMOCHRON® Jr. Microcoagulation ACT+ test cuvette including whole blood controls Normal / Abnormal
510(k) number: K941007
Manufacturer: International Technidyne Corporation (ITC), Edison, NJ

[D] 807.92 (a)(4): Device Description

The *directCHECK*® Whole Blood Controls are assayed lyophilized whole blood preparations intended for the quality control of quantitative coagulation tests. The *directCHECK*® whole blood control material is prepared from animal plasmas to which fixed animal red blood cells have been added. No human-based materials are contained in *directCHECK*® Whole Blood Controls. The whole blood control material is lyophilized in glass ampoules, and placed into an individual assembly with liquid diluent. When the glass ampoule is broken (activation of the assembly), the diluent rehydrates the lyophilized material, forming a liquid whole blood control.

[E] 807.92 (a)(5): Intended Use

The *directCHECK*® Whole Blood ACT-LR Level 1 (normal) and ACT-LR Level 2 (abnormal) Controls are assayed lyophilized whole blood preparations intended for the quality control of quantitative coagulation test: HEMOCHRON® ACT-LR assay on the HEMOCHRON® Jr. Signature+ and HEMOCHRON® Signature Elite instruments.

The *directCHECK*® Whole Blood ACT+ Level 1 (normal) and ACT+ Level 2 (abnormal) Controls are assayed lyophilized whole blood preparations intended for the quality control of quantitative coagulation test: HEMOCHRON® ACT+ assay on the HEMOCHRON® Jr. Signature+ and HEMOCHRON® Signature Elite instruments.

[G] 807.92 (a) (6): Technological Similarities and Differences to the Predicate

Each of the controls included in this submission has a unique predicate device as described in the tables below. For the *directCHECK*® Whole Blood Controls for HEMOCHRON® ACT-LR assay, the predicate device is HEMOCHRON® Jr. Microcoagulation Low Range ACT including whole blood controls cleared under 510(k) # K960749. Both products are two-level assayed whole blood controls used to monitor the integrity of point-of-care activated clotting time testing.

| CHARACTERISTIC | MODIFIED DEVICE: <i>directCHECK</i>® Whole Blood Controls for HEMOCHRON® ACT- LR Assay K120977 | PREDICATE DEVICE: HEMOCHRON® Jr. Microcoagulation Low Range ACT, JQC-ACT-LR K960749 |
|-----------------------|--|---|
| Intended Use | The <i>directCHECK</i> ® Whole Blood ACT-LR Level 1 (normal) and ACT-LR Level 2 (abnormal) Controls are assayed lyophilized whole blood preparations intended for the quality control of quantitative coagulation test: HEMOCHRON® ACT-LR assay on the HEMOCHRON® Jr. Signature+ and HEMOCHRON® Signature Elite instruments. | The HEMOCHRON® Jr. Microcoagulation Whole Blood Controls are lyophilized whole blood preparations which have been assayed and are intended to be used to perform quality control assays using the HEMOCHRON® Jr. Microcoagulation ACT-LR test cuvettes. |
| Material Composition | Non-human plasma, non-human red blood cells and diluent (containing calcium chloride). | Non-human plasma, non-human red blood cells, diluent and calcium chloride. |
| Form | Ready to use squeezable dropper containing liquid diluent and glass ampoule which contains lyophilized pellet. | Three vials: lyophilized control, diluent, and calcium chloride. |
| Storage | 2 to 8°C | 2 to 8° C non-punctured vials |
| Open Vial Claim | N/A, single-use, disposable, use immediately. | May be kept at room temperature for a maximum of one hour. |
| Procedural Steps | <ol style="list-style-type: none">1) Squeeze dropper to break glass ampoule inside2) Mix thoroughly by repeated inversion3) Dispense first drop into cap4) Dispense second drop onto the sample port of the cuvette | <ol style="list-style-type: none">1) Dispense diluent into control vial via syringe and swirl to rehydrate2) Stabilize at room temperature for 15 minutes then swirl to dissolve3) Add calcium chloride via syringe and agitate end to end4) Draw sample into syringe and dispense onto the sample port of the cuvette |
| Analyte | ACT-LR | ACT-LR |

The predicate device for the *directCHECK*® Whole Blood Controls for HEMOCHRON® ACT+ assay, is the HEMOCHRON® Jr. Microcoagulation ACT+ test cuvette including whole blood controls cleared in 510(k) # K941007. Both products are two-level assayed Whole Blood Controls used to monitor the integrity of point-of-care activated clotting time testing.

| CHARACTERISTIC | MODIFIED DEVICE: <i>directCHECK</i> ® Whole Blood Controls for HEMOCHRON® ACT+ Assay K1210977 | PREDICATE DEVICE: HEMOCHRON® Microcoagulation Activated Clotting Time PLUS (ACT+) test, QC-ACT+ K941007 |
|----------------------|--|--|
| Intended Use | The <i>directCHECK</i> ® Whole Blood ACT+ Level 1 (normal) and ACT+ Level 2 (abnormal) Controls are assayed lyophilized whole blood preparations intended for the quality control of quantitative coagulation test: HEMOCHRON® ACT+ assay on the HEMOCHRON® Jr. Signature+ and HEMOCHRON® Signature Elite instruments. | The ACT+ Quality Control Product is a lyophilized whole blood preparation that is used to perform a quality control assay using the HEMOCHRON® Jr. Microcoagulation ACT+ test cuvette. |
| Material Composition | Non-human plasma, non-human red blood cells and diluent (containing calcium chloride). | Non-human plasma, non-human red blood cells, diluent and calcium chloride. |
| Form | Ready to use squeezable dropper containing liquid diluent and glass ampoule which contains lyophilized pellet. | Three vials: lyophilized control, diluent, and calcium chloride. |
| Storage | 2 to 8°C | 4 to 8°C non-punctured vials |
| Open Vial Claim | N/A, single-use, disposable, use immediately | May be kept at room temperature for a maximum of one hour. |
| Procedural Steps | <ol style="list-style-type: none"> 1) Squeeze dropper to break glass ampoule inside 2) Mix thoroughly by repeated inversion 3) Dispense first drop into cap 4) Dispense second drop onto the sample port of the cuvette | <ol style="list-style-type: none"> 1) Dispense diluent into control vial via syringe and swirl to rehydrate 2) Stabilize at room temperature for 15 minutes then swirl to dissolve 3) Add calcium chloride via syringe and agitate end to end 4) Draw sample into syringe and dispense onto the sample port of the cuvette |
| Analyte | ACT+ | ACT+ |

Conclusion

Based on the product comparisons and the data provided in this submission, both the *directCHECK*® Whole Blood Quality Controls for the HEMOCHRON® ACT-LR assay and the *directCHECK*® Whole Blood Quality Controls for the HEMOCHRON® ACT+ assay are substantially equivalent to K960749 and K941007 respectively.

[H] 807.92 (b)(1): Brief Description of Nonclinical Data

Precision testing was performed according to CLSI Guideline EP5-A2. The *directCHECK*® Whole Blood Controls for HEMOCHRON® ACT-LR assay overall CV for Level 1 is 14%; this satisfies the Level 1 criteria of $\leq 14\%$. The overall CV for Level 2 is 10%; this satisfies the Level 2 acceptance criteria of $CV \leq 12\%$. The *directCHECK*® Whole Blood Controls for HEMOCHRON® ACT+ assay overall CV for Level 1 is 10%, the overall CV for Level 2 is 5%. This performance satisfies the acceptance criteria for each level at $CV \leq 12\%$.

Stability was evaluated following principles in CLSI Guideline EP25-A. Real time stability test results for the *directCHECK*® for the HEMOCHRON® ACT-LR assay demonstrates 5 months of shelf-life for Level 1 and for Level 2. Real time stability test results for *directCHECK*® for the HEMOCHRON® ACT+ assay demonstrates 5 months shelf-life for Level 1 and Level 2.

Room temperature stability was evaluated following principles in CLSI Guideline EP25-A. Room temperature test results for Level 1 and for Level 2 *directCHECK*® for the HEMOCHRON® ACT-LR assay and for the HEMOCHRON® ACT+ assay each demonstrate 4 weeks. These results support the labeled room temperature claim.

[I] 807.92 (b)(2): Brief Description of Clinical Data

This section is not applicable as clinical studies were not performed and there are no clinical data in this 510(k).

[J] 807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical test results including precision, shelf-life (stability) study, and room temperature (storage) test results for the *directCHECK*® Whole Blood Controls for HEMOCHRON® ACT-LR assay and for the *directCHECK*® Whole Blood Controls for HEMOCHRON® ACT+ assay are acceptable indicating the modified product is substantially equivalent to the predicate, as well as being safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

INTERNATIONAL TECHNIDYNE INC
C/O MR. LARRY PICCIANO
DIRECTOR REGULATORY AFFAIRS
23 NEVESKY ST.
EDISON, NJ. 08820

JULY 3, 2013

Re: k120977

Trade/Device Name: *direct*CHECK® for Hemochron Jr. Microcoagulation Systems ACT+
test cuvette
*direct*CHECK® for Hemochron Jr. Microcoagulation Systems ACT-
LR test cuvette

Regulation Number: 21 CFR 864.5425

Regulation Name: Multipurpose system for in vitro coagulation

Regulatory Class: Class II

Product Code: GGN

Dated: June 26, 2013

Received: June 27, 2013

Dear Mr. Picciano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRI's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological
Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120977

Device Name: directCHECK® Whole Blood ACT+
directCHECK® Whole Blood ACT-LR

Indications for Use:

The directCHECK® Whole Blood ACT+ Level 1 (normal) and ACT+ Level 2 (abnormal) Controls are assayed lyophilized whole blood preparations intended for the quality control of quantitative coagulation test: HEMOCHRON® ACT+ assay on the HEMOCHRON® Jr. Signature+ and HEMOCHRON® Signature Elite instruments.

The directCHECK® Whole Blood ACT-LR Level 1 (normal) and ACT-LR Level 2 (abnormal) Controls are assayed lyophilized whole blood preparations intended for the quality control of quantitative coagulation test: HEMOCHRON® ACT-LR assay on the HEMOCHRON® Jr. Signature+ and HEMOCHRON® Signature Elite instruments

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan.-S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k): k120977